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ATTY. DKT. NO. 10496/P581260ST

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

RECEIVED

In re Application of: Metin COLPAN

OCT 14 1999

Serial No.: 08/796,040

TC Art Unit: 1623 TECH CENTER 1600/2900

Filed: February 5, 1997

Examiner: L. Crane

For: DEVICE AND A PROCESS FOR THE ISOLATION OF NUCLEIC ACIDS

REPLY BRIEF

Assistant Commissioner of Patents  
Washington, D.C. 20231



Sir:

Appellant submits the instant Reply Brief to address issues newly raised in the Examiner's Answer, mailed August 11, 1999.

As a preliminary matter, the undersigned wishes to correct an inadvertent error made in Appellant's brief, filed July 2, 1999. At page 6 of Appellant's brief, under heading "B," addressing the rejection under 35 USC 112, 1<sup>st</sup> ¶, the statement appears: "Claim 117 does not recite 'mixture thereof,' the basis of the rejection (the term was deleted from corresponding appealed claim 79)." The foregoing quoted statement was made in error, by confusing claim 79 with claim 71, from which had been deleted "a combination thereof." Accordingly, the Examiner's Answer (at pages 5 and 6) is correct, in stating that claim 117 recites the term "or mixture thereof." The error, although inadvertent, is sincerely regretted.

As a further preliminary matter, in reviewing claim 117 to address the foregoing matter, it was appreciated for the first time that, as relating to the term "or mixture thereof," both the rejections under §112, first paragraph, and §112, second paragraph, might be the result of the scope afforded to the term "mixture thereof" by the Examiner in interpreting the claim. That is, claim 117 limits "the aqueous alcoholic solution" to that which contains recited molar amounts of ingredients "in 20% ethanol, propanol, isopropanol, butanol, poly(ethylene glycol), *or mixture thereof*" (emphasis added). In other words, the term "mixture thereof" refers only to the recited "ethanol, propanol, isopropanol, butanol, [and] poly(ethylene glycol)," which comprise "20%" of "the aqueous *alcoholic* solution" (emphasis added) recited at the beginning of the claim. Therefore, the molar concentrations of "1 to 7 M sodium perchlorate, from 1 to 7 M guanidine-HCl, from 1 to 5 M sodium chloride, from 1 to 6 M sodium iodide, and 1 M sodium chloride" are not modified by the term "mixture thereof." Whether the aforesaid explanation is considered probative by the Board, or by the Examiner, with respect to the §112, 1<sup>st</sup> ¶, and §112, 2<sup>nd</sup> ¶, rejections of claim 117, it is considered appropriate to bring this aspect of interpreting the claim to the attention of, both, the Board and the Examiner.

A new issue raised by the Examiner for the first time in his answer (Examiner's Answer, page 12) is the reliance on two references not previously of record, that is, *International Dictionary of Medicine and Biology*, Vol. 1, 1986 (New York) page 522, and *Nucleic Acid Hybridisation - A Practical Approach*, 1985 (Washington D.C.) pages

64, 65, and 235. The two new references are relied upon to allegedly show that Henco (relied upon in the statement of rejection) describes the use of "chaotropic" salts and, therefore, is allegedly appropriately combined with the teachings of Little (cited in the statement of rejection) which teaches the binding of nucleic acids found in a solution having a high concentration of "chaotropic" salts.

"An Examiner's answer must not include a new ground of rejection." 37 C.F.R. 1.193. "The criterion of whether a rejection is considered 'new' in a decision by the Board is whether appellants have had a fair opportunity to react to the thrust of the rejection. *In re Kronig*, 539 F.2d 1300, 190 USPQ 425 (CCPA 1976)." *Ex parte Maas*, 14 USPQ 2d 1762, 1764 (Bd. Pat. App. & Inter. 1990). The "procedure is improper" when a new reference relied upon by the Examiner "has not been [previously] relied upon as part of the rejection of the claims." *Ex parte Titone*, 177 USPQ 731, 733 (PO Bd App 1971). When rejection based on prior art cannot be sustained without citing "two new references", it is improper to maintain the earlier rejection and a new rejection is needed since "there would appear to be no excuse" for not previously citing the two new references. *Ex parte Jeannet*, 173 USPQ 512 (PO Dir. 1970).

The Examiner's answer cites and relies on, for the first time, two references to support a § 103 rejection; i.e., in order to show that one of ordinary skill in the art would have combined the teachings of the two references originally relied upon in the statement of rejection. Appellant has never had a "fair opportunity" to address

whether, in fact, these newly cited references support the proposition on which they are relied upon by the Examiner. Therefore, the "criterion" of the "Board" is satisfied that citing these two new references amounts to a "new" (ground of) rejection. *Maas, supra*. Having "not been relied upon as part of the rejection of the claims" until cited in the Examiner's answer, the "procedure is improper." *Titone, supra*. Without the newly cited references, there is no *alleged* evidence of record linking the "chaotropic" salts used in the Little reference with the substances described in Henco. Accordingly, appellant respectfully requests that the Board refuse to consider the references newly cited as not properly having been made of record during prosecution. *Jeannet, supra*.

In any event, Appellant respectfully submits that the two newly cited references add nothing to cure the fatal deficiencies found in the Henco and Little references, as explained in detail in Applicant's brief (filed July 2, 1999). The Examiner relies on the two newly cited references to allegedly show that materials disclosed in the previously cited prior art fall within the definition of "chaotropic agents." However, even assuming, *arguendo*, the Examiner is correct, the Examiner acknowledges that the "Henco reference does not make specific reference to a chaotropic agent" (Examiner's answer, page 12, lines 25-26). Whether or not, however, materials described by Henco accidentally fall within a broad definition of "chaotropic agent," Henco neither teaches nor suggests use of these materials for their allegedly *chaotropic* function. Therefore, even should the newly cited references show that materials described in the originally cited prior art fall within the definition of chaotropic agent, there remains no

teaching or suggestion in the prior art for using these materials as chaotropic agents; and, the Examiner's argument that they might function as such provides no reason or motivation for one of ordinary skill in the art to combine the materials in the manner presently claimed. Claims do not read on the prior art if "chemicals, although present in the prior art, were used for other non- . . . [claimed] functions and did not [perform the claimed function] . . . as . . . understood from the . . . specification." *Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc.*, 24 USPQ 2d 1321, 1327 (Fed. Cir. 1992).

In the "Response to Argument" in the Examiner's answer as it applies to the rejection of rejection under 35 U.S.C. 103, the Examiner discounts Appellant's argument "because Appellant has failed to provide a clear statement of how the combination of Henco et al. and Little has in any way destroyed the invention of Little as delineated by the claims found at the end of Little" (Examiner's answer, page 19, emphasis in original). With all due respect, the Examiner's reliance on the "claims found at the end of Little" as to what Little taught to one of ordinary skill in the art is misplaced. It is well-established that a patent's *claims* are no measure of what a patent discloses for prior art purposes of 35 U.S.C. 102 and 103. *In re Benno*, 226 USPQ 683 (Fed. Cir. 1985). Indeed, it is the teachings of Little, as a whole, not merely those of Little's claims that must be applied to the presently claimed invention for purposes of analysis under §103 of the statute.

At page 13 of his answer, the Examiner characterizes "Appellant's arguments at the top of page 9 [of the Appeal brief] that the use of the increased salt concentrations required by Little's desalting process would be counterintuitive and therefore destroy the motivation provided by Henco." With all due respect, Appellant made no argument about destroying "the motivation provided by Henco"; it is the motivation alleged by the Examiner to be found in the prior art, which Appellant disputes. It is the combined teachings of the prior art, taken as a whole, which must be considered in an obviousness analysis. *Ryko Manufacturing Co. v. Nu-Star, Inc.*, 21 USPQ 2d 1053 (Fed. Cir. 1991). Therefore, increasing the salt concentration in accordance with the teachings of Little is *not* "irrelevant to the question of motivation" to combine the prior art, contrary to the Examiner's argument (Examiner's answer, page 13, line 27 - page 14, line 1).

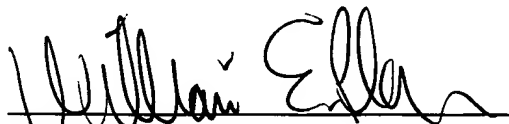
A further new issue raised in the Examiner's answer is the argument that the "choice of a specific chaotropic agent to be included in an elution buffer is a variation in chromatographic procedure which Examiner asserts is clearly within the perview [*sic*] of the ordinary practitioner unless applicant has shown unexpected results" (Examiner's answer, page 13). The alleged "variation in chromatographic procedure" being within the knowledge "of the ordinary practitioner" merely points out that the skilled artisan would have known *how* to vary the chromatographic procedure taught in the prior art had the skilled artisan thought up the *idea* of doing so, in the first place. With all due respect, the Examiner's argument fails to take into account that *invention*

comprises both the *idea* of the invention and the *means* to achieve that idea. *In re Cocer*, 175 USPQ 26 (CCPA 1972). Both the idea and means to achieve the idea must be evidenced in the prior art in order to demonstrate lack of patentability. *Id.* That a difference with the prior art amounts to an alleged "optimal condition" is "not a substitute for some teaching or suggestion supporting an obviousness rejection." *In re Rijckaert*, 28 USPQ 2d 1955, 1957 (Fed. Cir. 1993). Again, both the *idea* and the *means* to achieve the idea must be evidenced in the prior art in order to show obviousness. *In re Hoffman*, 37 USPQ 222 (CCPA 1938). "That which is within the capabilities of one skilled in the art is not synonymous with obviousness [citations omitted]. *Ex parte Levensgood*, 28 USPQ 2d 1300, 1302 (Bd. Pat. App. & Inter. 1993). Whether or not Little accidentally uses a substance that happens to be, assuming *arguendo*, a chaotropic agent, but does not use it for that purpose, does not suggest use of the material as a chaotropic agent to one of ordinary skill in the art. *Minnesota Mining & Manufacturing Co., supra.*

For the foregoing reasons, in conjunction with the reasons set forth in Appellant's brief, reversal of the rejections of record is respectfully requested.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'William E. Player', written over a horizontal line.

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